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6 Attorneys for Defendants  
7 ORTHO-MCNEIL PHARMACEUTICAL, INC., now  
known as ORTHO-McNEIL-JANSSEN  
8 PHARMACEUTICALS, INC.,  
and MCKESSON CORPORATION

12 THERESA CLEMONDS, an individual;  
13 VALERI HAMILTON, an individual;  
14 CLAUDIA MATAMOROS, an individual;  
15 LATASHA PRENTICE, an individual;  
MARGARET RAINY, an individual;  
FELECIA SOUTHWELL, an individual;  
HALEY VANSANDT, an individual;

16 Plaintiffs,

17

18 ORTHO-MCNEIL PHARMACEUTICAL,  
19 INC., a Delaware Corporation;  
MCKESSON CORP. and DOES 1-500,  
inclusive.

Defendants.

22 Defendants Ortho-McNeil Pharmaceutical, Inc. (“OMP”), now known as Ortho-  
23 McNeil-Janssen Pharmaceuticals, Inc. (“OMJPI”), and McKesson Corporation (“McKesson”)  
24 (collectively “Defendants”), by and through counsel, hereby respond to the allegations set  
25 forth in Plaintiffs’ Complaint (the “Complaint”), as follows:

## **ANSWER TO INTRODUCTION**

1. Defendants are without knowledge or information sufficient to form a belief as to Plaintiffs' allegations that they used ORTHO EVRA®. Defendants deny the

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remaining allegations contained in paragraph 1 of Plaintiffs' Complaint.

2. Defendants admit that OMP, now known as OMPJI, manufactured, advertised, promoted, marketed, sold and distributed ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 2 of Plaintiffs' Complaint.

3. Defendants admit that McKesson is a non-exclusive distributor of ORTHO EVRA® and has its principal place of business in San Francisco, California. Defendants deny the remaining allegations contained in paragraph 3 of Plaintiffs' Complaint.

4. Defendants admit that on the ORTHO EVRA® Web site, it stated that: "The transdermal -- or 'through the skin' -- weekly birth control patch prevents pregnancy by delivering continuous levels of the hormones norelgestromin and ethinyl estradiol (progestin and estrogen, respectively) through the skin and into the bloodstream." Defendants admit that the FDA approved the use of ORTHO EVRA® for the prevention of pregnancy in November 2001. Defendants further admit that the FDA's publications state what they state. Defendants deny the remaining allegations contained in paragraph 4 of Plaintiffs' Complaint.

## **ANSWER TO JURISDICTION AND VENUE**

5. Paragraph 5 of Plaintiffs' Complaint contains legal conclusions to which no response is required.

6. Defendants admit that OMP, now known as OMPJI, was a Delaware corporation with its principal place of business in New Jersey, that OMPJI is a Pennsylvania corporation with its principal place of business in New Jersey, and that McKesson is a Delaware corporation with its principal place of business in California. Defendants deny the remaining allegations contained in paragraph 6 of Plaintiffs' Complaint.

7. Defendants admit that McKesson has its principal place of business in San Francisco, California. Defendants deny the remaining allegations contained in paragraph 7 of Plaintiffs' Complaint.

8. Defendants admit that McKesson has its principal place of business in San

1 Francisco, California. Defendants deny the remaining allegations contained in paragraph  
2 8 of Plaintiffs' Complaint.

3 9. Defendants are without knowledge or information sufficient to form a  
4 belief as to the allegations contained in paragraph 9 of Plaintiffs' Complaint.

5 **ANSWER TO PLAINTIFFS**

6 10. Defendants are without knowledge or information sufficient to form a  
7 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed  
8 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 10  
9 of Plaintiffs' Complaint.

10 11. Defendants are without knowledge or information sufficient to form a  
12 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed  
13 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 11  
14 of Plaintiffs' Complaint.

15 12. Defendants are without knowledge or information sufficient to form a  
16 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed  
17 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 12  
18 of Plaintiffs' Complaint.

19 13. Defendants are without knowledge or information sufficient to form a  
20 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed  
21 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 13  
22 of Plaintiffs' Complaint.

23 14. Defendants are without knowledge or information sufficient to form a  
24 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed  
25 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 14  
26 of Plaintiffs' Complaint.

27 15. Defendants are without knowledge or information sufficient to form a  
28 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed  
ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 15

1 of Plaintiffs' Complaint.  
2

3 16. Defendants are without knowledge or information sufficient to form a  
4 belief as to where Plaintiff resides or Plaintiff's allegations that she was prescribed  
5 ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 16  
6 of Plaintiffs' Complaint.

7 **ANSWER TO DEFENDANTS**

8 17. Defendants admit that OMP, now known as OMPJI, was a Delaware  
9 corporation with its principal place of business in New Jersey and that OMPJI is a  
10 Pennsylvania corporation with its principal place of business in New Jersey. Defendants  
11 deny the remaining allegations contained in paragraph 17 of Plaintiffs' Complaint.

12 18. Defendants admit that OMP, now known as OMPJI, conducts business in  
13 California. Defendants deny the remaining allegations contained in paragraph 18 of  
14 Plaintiffs' Complaint.

15 19. Defendants are without knowledge or information sufficient to form a  
16 belief as to the allegations contained in paragraph 19 of Plaintiffs' Complaint, and  
17 therefore these allegations are denied.

18 20. Defendants are without knowledge or information sufficient to form a  
19 belief as to the allegations contained in paragraph 20 of Plaintiffs' Complaint, and  
20 therefore these allegations are denied.

21 21. Defendants admit that OMP, now known as OMPJI, manufactured,  
22 marketed, promoted, sold and distributed ORTHO EVRA®. Defendants deny the  
23 remaining allegations contained in paragraph 21 of Plaintiffs' Complaint.

24 22. Defendants admit that McKesson is a Delaware corporation with its  
25 principal place of business in San Francisco, California. Defendants further admit that  
26 McKesson conducts business in California. Defendants deny the remaining allegations  
27 contained in paragraph 22 of Plaintiffs' Complaint.

28 22. Defendants are without knowledge or information sufficient to form a  
belief as to the allegations contained in paragraph 23 of Plaintiffs' Complaint, and

therefore these allegations are denied.

24. Defendants are without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 24 of Plaintiffs' Complaint, and therefore these allegations are denied.

25. Defendants admit that McKesson is a non-exclusive distributor of ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 25 of Plaintiffs' Complaint.

26. Defendants are without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 26 of Plaintiffs' Complaint.

27. Defendants are without knowledge or information sufficient to form a belief as to the allegations contained in paragraph 27 of Plaintiffs' Complaint.

28. To the extent that paragraph 28 of Plaintiffs' Complaint alleges improper conduct on the part of Defendants, such allegations are denied.

29. To the extent that paragraph 29 of Plaintiffs' Complaint alleges improper conduct on the part of Defendants, such allegations are denied.

## **ANSWER TO GENERAL ALLEGATIONS**

30. OMP, now known as OMPJI, admits that on the OMP Web site, it stated that: "Ortho-McNeil Pharmaceutical is a pioneer in contraception and a leader in women's health care. Ortho-McNeil offers the broadest range of prescription birth control options..." OMP, now known as OMPJI, further admits that it manufactures and sells ORTHO EVRA®, the first combination transdermal contraceptive patch. Defendants deny the remaining allegations contained in paragraph 30 of Plaintiffs' Complaint.

31. OMP, now known as OMPJI, admits that ORTHO EVRA® is the first and only once-a-week birth control patch. OMP, now known as OMPJI, further admits that on the ORTHO EVRA® Web site, it stated that: "The transdermal -- or 'through the skin' -- weekly birth control patch prevents pregnancy by delivering continuous levels of the hormones norelgestromin and ethynodiol (progesterone and estrogen, respectively)

1 through the skin and into the bloodstream." Defendants deny the remaining allegations  
 2 contained in paragraph 31 of Plaintiffs' Complaint.  
 3

4       32. Defendants admit that a New Drug Application ("NDA") was filed for  
 5 ORTHO EVRA®, denoted as 21-180, with the FDA in December 2000. Defendants  
 6 further admit that the FDA Medical Officer's Review for ORTHO EVRA® states what it  
 7 states. Defendants deny the remaining allegations contained in paragraph 32 of  
 8 Plaintiffs' Complaint.  
 9

10      33. Defendants admit that the FDA approved the use of ORTHO EVRA® for  
 11 the prevention of pregnancy in November 2001. Defendants deny the remaining  
 12 allegations contained in paragraph 33 of Plaintiffs' Complaint.  
 13

14      34. Defendants admit that as with all prescription medicine, adverse events are  
 15 reported to the FDA by a variety of people and entities. Defendants deny the remaining  
 16 allegations contained in paragraph 34 of Plaintiffs' Complaint.  
 17

18      35. Defendants admit that the FDA's publications state what they state.  
 19 Defendants deny the remaining allegations contained in paragraph 35 of Plaintiffs'  
 20 Complaint.  
 21

22      36. Defendants admit that the November 2005 package insert for ORTHO  
 23 EVRA® states what it states. To the extent that paragraph 36 of Plaintiffs' Complaint  
 24 alleges improper conduct on the part of Defendants, such allegations are denied.  
 25

26      37. OMP, now known as OMPJI, admits that ORTHO EVRA® is the first and  
 27 only once-a-week birth control patch. Defendants deny the remaining allegations  
 28 contained in paragraph 37 of Plaintiffs' Complaint.  
 29

30      38. Defendants deny the allegations contained in paragraph 38 of Plaintiffs'  
 31 Complaint.  
 32

33      39. Defendants admit that the package insert for ORTHO EVRA® states what  
 34 it states. To the extent that paragraph 39 of Plaintiffs' Complaint alleges improper  
 35 conduct on the part of Defendants, such allegations are denied.  
 36

37      40. Defendants deny the allegations contained in paragraph 40 of Plaintiffs'  
 38

## Complaint.

41. Defendants state that they were subject only to those duties imposed by applicable law, and deny the allegations contained in paragraph 41 of Plaintiffs' Complaint to the extent they suggest any different or greater duties. Defendants further deny that they failed to abide by any applicable legal duties.

42. Defendants deny the allegations contained in paragraph 42 of Plaintiffs' Complaint.

43. Defendants deny the allegations contained in paragraph 43 of Plaintiffs' Complaint.

44. Defendants deny the allegations contained in paragraph 44 of Plaintiffs' Complaint.

45. Defendants deny the allegations contained in paragraph 45 of Plaintiffs' Complaint.

## **ANSWER TO FRAUDULENT CONCEALMENT**

46. Defendants deny the allegations contained in paragraph 46 of Plaintiffs' Complaint.

47. Defendants state that they were subject only to those duties imposed by applicable law, and deny the allegations contained in paragraph 47 of Plaintiffs' Complaint to the extent they suggest any different or greater duties. Defendants further deny that they failed to abide by any applicable legal duties, and deny the remaining allegations contained in this paragraph.

## **ANSWER TO FIRST CAUSE OF ACTION**

## **NEGLIGENCE**

48. Defendants repeat their answers to the allegations of paragraphs 1 through  
47 of Plaintiffs' Complaint as if set forth at length herein.

49. Defendants state that they were subject only to those duties imposed by applicable law, and deny the allegations contained in paragraph 49 of the First Cause of Action of Plaintiffs' Complaint to the extent they suggest any different or greater duties.

Defendants further deny that they failed to abide by any applicable legal duties.

50. Defendants deny the allegations contained in paragraph 50 of the First Cause of Action of Plaintiffs' Complaint.

51. Defendants deny the allegations contained in paragraph 51 of the First Cause of Action of Plaintiffs' Complaint.

52. Defendants deny the allegations contained in paragraph 52 of the First Cause of Action of Plaintiffs' Complaint.

53. Defendants deny the allegations contained in paragraph 53 of the First Cause of Action of Plaintiffs' Complaint.

54. Defendants deny the allegations contained in paragraph 54 of the First Cause of Action of Plaintiffs' Complaint.

55. Defendants deny the allegations contained in paragraph 55 of the First Cause of Action of Plaintiffs' Complaint.

56. Defendants deny the allegation that ORTHO EVRA® is defective, and deny the remaining allegations contained in paragraph 56 of the First Cause of Action of Plaintiffs' Complaint.

57. Defendants deny the allegations contained in paragraph 57 of the First Cause of Action of Plaintiffs' Complaint.

58. Defendants deny the allegations contained in paragraph 58 of the First Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in the unnumbered paragraph following paragraph 58.

## **ANSWER TO SECOND CAUSE OF ACTION**

## **STRICT PRODUCT LIABILITY – FAILURE TO WARN**

59. Defendants repeat their answers to the allegations of paragraphs 1 through 58 of Plaintiffs' Complaint as if set forth at length herein.

60. Defendants admit that OMP, now known as OMPJI, manufactures and supplies ORTHO EVRA®. Defendants deny the remaining allegations contained in paragraph 60 of the Second Cause of Action of Plaintiffs' Complaint.

1       61. Defendants admit that OMP, now known as OMPJI, manufactures and  
2 supplies ORTHO EVRA®. Defendants deny the remaining allegations contained in  
3 paragraph 61 of the Second Cause of Action of Plaintiffs' Complaint.

4       62. Defendants deny the allegations contained in paragraph 62 of the Second  
5 Cause of Action of Plaintiffs' Complaint.

6       63. Defendants deny the allegation that ORTHO EVRA® is defective, and  
7 deny the remaining allegations contained in paragraph 63 of the Second Cause of Action  
8 of Plaintiffs' Complaint.

9       64. Defendants deny the allegation that ORTHO EVRA® is defective, and  
10 deny the remaining allegations contained in paragraph 64 of the Second Cause of Action  
11 of Plaintiffs' Complaint.

12       65. Defendants deny the allegations contained in paragraph 65 of the Second  
13 Cause of Action of Plaintiffs' Complaint.

14       66. Defendants deny the allegation that ORTHO EVRA® is defective, and  
15 deny the remaining allegations contained in paragraph 66 of the Second Cause of Action  
16 of Plaintiffs' Complaint.

17       67. Defendants deny the allegations contained in paragraph 67 of the Second  
18 Cause of Action of Plaintiffs' Complaint.

19       68. Defendants deny the allegations contained in paragraph 68 of the Second  
20 Cause of Action of Plaintiffs' Complaint.

21       69. Defendants deny the allegations contained in paragraph 69 of the Second  
22 Cause of Action of Plaintiffs' Complaint.

23       70. Defendants deny the allegations contained in paragraph 70 of the Second  
24 Cause of Action of Plaintiffs' Complaint.

25       71. Defendants deny the allegations contained in paragraph 71 of the Second  
26 Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in  
27 the unnumbered paragraph following paragraph 71.

1  
ANSWER TO THIRD CAUSE OF ACTION

2  
**BREACH OF EXPRESS WARRANTY**

3  
72. Defendants repeat their answers to the allegations of paragraphs 1 through  
4  
71 of Plaintiffs' Complaint as if set forth at length herein.

5  
73. Defendants deny the allegations contained in paragraph 73 of the Third  
6  
Cause of Action of Plaintiffs' Complaint.

7  
74. Defendants deny the allegations contained in paragraph 74 of the Third  
8  
Cause of Action of Plaintiffs' Complaint.

9  
75. Defendants deny the allegations contained in paragraph 75 of the Third  
10  
Cause of Action of Plaintiffs' Complaint.

11  
76. Defendants deny the allegations contained in paragraph 76 of the Third  
12  
Cause of Action of Plaintiffs' Complaint.

13  
77. Defendants deny the allegations contained in paragraph 77 of the Third  
14  
Cause of Action of Plaintiffs' Complaint.

15  
78. Defendants deny the allegations contained in paragraph 78 of the Third  
16  
Cause of Action of Plaintiffs' Complaint.

17  
79. Defendants deny the allegations contained in paragraph 79 of the Third  
18  
Cause of Action of Plaintiffs' Complaint.

19  
80. Defendants deny the allegations contained in paragraph 80 of the Third  
20  
Cause of Action of Plaintiffs' Complaint.

21  
81. Defendants deny the allegations contained in paragraph 81 of the Third  
22  
Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in  
23  
the unnumbered paragraph following paragraph 81.

24  
**ANSWER TO FOURTH CAUSE OF ACTION**

25  
**BREACH OF IMPLIED WARRANTY**

26  
82. Defendants repeat their answers to the allegations of paragraphs 1 through  
27  
81 of Plaintiffs' Complaint as if set forth at length herein.

28  
83. Defendants admit that OMP, now known as OMPJI, marketed, sold and

1 distributed ORTHO EVRA®, which is used for the prevention of pregnancy. Defendants  
 2 further admit that McKesson is a non-exclusive distributor of ORTHO EVRA®, and  
 3 deny that McKesson marketed or sold ORTHO EVRA®. The remainder of paragraph 83  
 4 of the Fourth Cause of Action of Plaintiffs' Complaint contains a legal conclusion to  
 5 which no response is required.

6       84. Paragraph 84 of the Fourth Cause of Action of Plaintiffs' Complaint  
 7 contains legal conclusions to which no response is required.

8       85. Defendants are without knowledge or information sufficient to form a  
 9 belief as to the allegations contained in paragraph 85 of the Fourth Cause of Action of  
 10 Plaintiffs' Complaint, and therefore these allegations are denied.

11      86. Defendants deny the allegations contained in paragraph 86 of the Fourth  
 12 Cause of Action of Plaintiffs' Complaint.

13      87. Defendants deny the allegations contained in paragraph 87 of the Fourth  
 14 Cause of Action of Plaintiffs' Complaint.

15      88. Defendants deny the allegations contained in paragraph 88 of the Fourth  
 16 Cause of Action of Plaintiffs' Complaint.

17      89. Defendants deny the allegations contained in paragraph 89 of the Fourth  
 18 Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in  
 19 the unnumbered paragraph following paragraph 89.

## 21                   **ANSWER TO FIFTH CAUSE OF ACTION**

### 22                   **NEGLIGENT MISREPRESENTATION**

23      90. Defendants repeat their answers to the allegations of paragraphs 1 through  
 24 89 of Plaintiffs' Complaint as if set forth at length herein.

25      91. Defendants admit that OMP, now known as OMPJI, manufactures,  
 26 markets, promotes, and sells ORTHO EVRA®. Defendants further state that they were  
 27 subject only to those duties imposed by applicable law, and deny the allegations  
 28 contained in this paragraph to the extent they suggest any different or greater duties.  
 Defendants further deny that they failed to abide by any applicable legal duties, and deny

the remaining allegations contained in paragraph 91 of the Fifth Cause of Action of Plaintiffs' Complaint.

92. Defendants deny the allegations contained in paragraph 92 of the Fifth Cause of Action of Plaintiffs' Complaint.

93. Defendants deny the allegations contained in paragraph 93 of the Fifth Cause of Action of Plaintiffs' Complaint.

94. Defendants deny the allegations contained in paragraph 94 of the Fifth Cause of Action of Plaintiffs' Complaint.

95. Defendants deny the allegations contained in paragraph 95 of the Fifth Cause of Action of Plaintiffs' Complaint.

96. Defendants deny the allegations contained in paragraph 96 of the Fifth Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in the unnumbered paragraph following paragraph 96.

**ANSWER TO SIXTH CAUSE OF ACTION**

**FRAUD**

97. Defendants repeat their answers to the allegations of paragraphs 1 through  
96 of Plaintiffs' Complaint as if set forth at length herein.

98. Defendants admit that OMP, now known as OMPJI, manufactures, markets, promotes, and sells ORTHO EVRA®. Defendants further state that they were subject only to those duties imposed by applicable law, and deny the allegations contained in this paragraph to the extent they suggest any different or greater duties. Defendants further deny that they failed to abide by any applicable legal duties, and deny the remaining allegations contained in paragraph 98 of the Sixth Cause of Action of Plaintiffs' Complaint.

99. Defendants deny the allegations contained in paragraph 99 of the Sixth Cause of Action of Plaintiffs' Complaint.

100. Defendants deny the allegations contained in paragraph 100 of the Sixth Cause of Action of Plaintiffs' Complaint.

101. Defendants deny the allegations contained in paragraph 101 of the Sixth Cause of Action of Plaintiffs' Complaint.

102. Defendants deny the allegations contained in paragraph 102 of the Sixth Cause of Action of Plaintiffs' Complaint.

103. Defendants deny the allegations contained in paragraph 103 of the Sixth Cause of Action of Plaintiffs' Complaint.

104. Defendants deny the allegations contained in paragraph 104 of the Sixth Cause of Action of Plaintiffs' Complaint.

105. Defendants deny the allegations contained in paragraph 105 of the Sixth Cause of Action of Plaintiffs' Complaint.

106. Defendants are without knowledge or information sufficient to form a belief as to Plaintiffs' states of mind. Defendants deny the remaining allegations contained in paragraph 106 of the Sixth Cause of Action of Plaintiffs' Complaint.

107. Defendants deny the allegations contained in paragraph 107 of the Sixth Cause of Action of Plaintiffs' Complaint.

108. Defendants deny the allegations contained in paragraph 108 of the Sixth Cause of Action of Plaintiffs' Complaint.

109. Defendants deny the allegations contained in paragraph 109 of the Sixth Cause of Action of Plaintiffs' Complaint.

110. Defendants deny the allegations contained in paragraph 110 of the Sixth Cause of Action of Plaintiffs' Complaint and controvert the prayers for relief set forth in the unnumbered paragraph following paragraph 110.

## **FIRST AFFIRMATIVE DEFENSE**

Plaintiffs' Complaint fails to state a claim against Defendants upon which relief may be granted.

## **SECOND AFFIRMATIVE DEFENSE**

Venue is improper in this court.

### **THIRD AFFIRMATIVE DEFENSE**

Plaintiffs are fraudulently joined and/or misjoined, and the court should sever Plaintiffs' claims and/or enter other appropriate orders to avoid prejudice, unfairness, hardship, delay, and undue expense and to promote convenience and expedience.

#### **FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred, in whole or in part, to the extent certain Plaintiffs have asserted duplicative claims in one or more other actions pending against some or all of the same defendants.

## **FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred by the applicable statute of limitations, statute of repose and/or by the equitable doctrines of laches and estoppel.

## **SIXTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred by the doctrines of informed consent, release and waiver.

## **SEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred because the alleged damages, if any are proven, were not proximately caused by any act or omission of any of the Defendants.

## **EIGHTH AFFIRMATIVE DEFENSE**

If Plaintiffs suffered any of the injuries, losses and damages alleged, then said injuries, losses and damages were a direct and proximate result of a responsible, superseding, and/or intervening cause.

## NINTH AFFIRMATIVE DEFENSE

Defendants state that if Plaintiffs have suffered any of the injuries, losses and damages alleged, then said injuries, losses and damages were due to an allergic, idiosyncratic or idiopathic reaction to the product at issue in this case, or by an unforeseeable illness, unavoidable accident or preexisting condition, without any

1 negligence and culpable conduct by Defendants.  
 2

3 **TENTH AFFIRMATIVE DEFENSE**

4 Plaintiffs' injuries and damages, if any, were caused in whole or in part by the acts  
 5 (wrongful or otherwise), negligence, sole fault, misuse, abuse, modification, alteration,  
 6 omission or fault of one or more persons or entities over whom Defendants exercised no  
 7 control and for whom Defendants are not legally responsible, including, without  
 8 limitation, Plaintiffs.

9 **ELEVENTH AFFIRMATIVE DEFENSE**

10 Plaintiffs failed to exercise reasonable care and diligence to mitigate injuries and  
 11 damages, if any.

12 **TWELFTH AFFIRMATIVE DEFENSE**

13 Plaintiffs' claims are barred by the "state of the art" and "state of scientific  
 14 knowledge" defenses.

15 **THIRTEENTH AFFIRMATIVE DEFENSE**

16 Plaintiffs' claims are barred by the Learned Intermediary Doctrine.

17 **FOURTEENTH AFFIRMATIVE DEFENSE**

18 The product at issue in this case falls under the auspices of the Food, Drug and  
 19 Cosmetic Act and regulations promulgated by the Federal Food & Drug Administration,  
 20 and therefore, Federal law preempts Plaintiffs' claims. *See*, 21 U.S.C. §301 *et. seq.* *See*  
 21 *also*, 71 Fed. Reg. 3922 (January 24, 2006).

22 **FIFTEENTH AFFIRMATIVE DEFENSE**

23 Defendants did not make to Plaintiffs nor did they breach any express or implied  
 24 warranties and/or breach any warranties created by law. To the extent that Plaintiffs rely  
 25 on any theory of breach of warranty, such claims are barred by applicable law, and for  
 26 lack of privity with Defendants and/or for failure of Plaintiffs, or Plaintiffs'  
 27 representatives, to give timely notice to Defendants of any alleged breach of warranty.

1 Plaintiffs did not rely on any alleged warranty. Defendants further specifically plead as  
 2 to any breach of warranty claim all affirmative defenses under the Uniform Commercial  
 3 Code existing and which may arise in the future, as enacted in the State of California, and  
 4 any other state whose law is deemed to apply in this case.  
 5

6 **SIXTEENTH AFFIRMATIVE DEFENSE**

7 Plaintiffs' claims are barred by comments j and k to Section 402A of the  
 8 Restatement (Second) of Torts.

9 **SEVENTEENTH AFFIRMATIVE DEFENSE**

10 Plaintiffs' claims of product defects are barred by Section 2, 4, and 6(c) and (d) of  
 11 the Restatement (Third) of Torts: Products Liability.

12 **EIGHTEENTH AFFIRMATIVE DEFENSE**

13 Plaintiffs' product liability claims are barred because the benefits of the relevant  
 14 product outweighed its risks.

15 **NINETEENTH AFFIRMATIVE DEFENSE**

16 Plaintiffs' claims are barred in whole or part because the product at issue was at all  
 17 times properly prepared, packaged, and distributed, and was not defective or  
 18 unreasonably dangerous.

19 **TWENTIETH AFFIRMATIVE DEFENSE**

20 Any imposition of punitive damages in this case against Defendants is barred to  
 21 the extent that the manner in which such punitive damages are calculated violates the  
 22 Constitution of the United States or the Constitution of the State of California.  
 23

24 **TWENTY-FIRST AFFIRMATIVE DEFENSE**

25 Any award of punitive damages in this case against Defendants is barred to the  
 26 extent that the amount of such an award violates the Constitution of the United States or  
 27 the Constitution of the State of California.  
 28

## **TWENTY-SECOND AFFIRMATIVE DEFENSE**

Plaintiffs have failed to plead fraud with specificity.

## **TWENTY-THIRD AFFIRMATIVE DEFENSE**

Defendants are entitled to a setoff for all amounts paid, payable by or available from collateral sources.

## **TWENTY-FOURTH AFFIRMATIVE DEFENSE**

The Complaint fails to state a cause of action against Defendants because there is no private right of action under the applicable federal law. To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to FDA, such claims are barred pursuant to *Buckman v. Plaintiffs' Legal Community*, 531 U.S. 341 (2001).

## **TWENTY-FIFTH AFFIRMATIVE DEFENSE**

Plaintiffs knowingly and voluntarily assumed any and all risks associated with the use of the product at issue, barring in whole or in part the damages Plaintiffs seek to recover.

## **TWENTY-SIXTH AFFIRMATIVE DEFENSE**

In the event Defendants, or any of them, are held liable to Plaintiffs, or any of them, which liability is expressly denied, or a settlement of judgment against Defendants, or any of them, is reached, Defendants request an apportionment of fault be made as permitted by *Li v. Yellow Cab Company*, 13 Cal.3d 804 (1975) and *American Motorcycle Association v. Superior Court*, 20 Cal.3d 578 (1987) and a judgment and declaration of indemnification and contribution be entered against all other persons and entities in accordance with that apportionment of fault.

## **TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

The amount of any award on behalf of Plaintiffs, or any of them, for non-economic loss must be allocated according to the provisions of California Civil Code Section 1431.2 (“Proposition 51”).

## **TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

Defendants specifically reserve the right to amend their Answer by adding defenses, counterclaims, cross claims or by instituting third party actions as additional facts are obtained.

WHEREFORE, having fully answered, Defendants specifically controvert Plaintiffs' Prayer for Relief including Paragraphs (1)-(6).

**JURY DEMAND**

Defendants hereby demand a trial by jury of all the facts and issues in this case pursuant to Federal Rule of Civil Procedure 38(b).

Dated: February 26, 2008

DRINKER BIDDLE & REATH

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BRENDA N. BUONAIUTO  
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ORTHO-MCNEIL PHARMACEUTICAL,  
INC., now known as ORTHO-MCNEIL-  
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